



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2016-N-0001]

Advisory Committee; Drug Safety and Risk Management Advisory Committee, Renewal

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; renewal of advisory committee.

SUMMARY: The Food and Drug Administration (FDA) is announcing the renewal of the Drug Safety and Risk Management Advisory Committee by the Commissioner of Food and Drugs (the Commissioner). The Commissioner has determined that it is in the public interest to renew the Drug Safety and Risk Management Advisory Committee for an additional 2 years beyond the charter expiration date. The new charter will be in effect until May 31, 2018.

DATES: Authority for the Drug Safety and Risk Management Advisory Committee will expire on May 31, 2016, unless the Commissioner formally determines that renewal is in the public interest.

FOR FURTHER INFORMATION CONTACT: Philip A. Bautista, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, rm. 2417, Silver Spring, MD 20993-0002, 301-796-9001, DSARM@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Pursuant to 41 CFR 102-3.65 and approval by the Department of Health and Human Services pursuant to 45 CFR part 11 and by the General Services Administration, FDA is announcing the renewal of the Drug Safety and Risk Management Advisory Committee. The committee is a discretionary Federal advisory committee established to provide advice to the Commissioner. The Drug Safety and Risk

Management Advisory Committee advises the Commissioner or designee in discharging responsibilities as they relate to helping to ensure safe and effective drugs for human use and, as required, any other product for which the Food and Drug Administration has regulatory responsibility. The Committee reviews and evaluates information on risk management, risk communication, and quantitative evaluation of spontaneous reports for drugs for human use and for any other product for which the Food and Drug Administration has regulatory responsibility. The Committee also advises the Commissioner of Food and Drugs regarding the scientific and medical evaluation of all information gathered by the Department of Health and Human Services and the Department of Justice with regard to safety, efficacy, and abuse potential of drugs or other substances, and recommends actions to be taken by the Department of Health and Human Services with regard to the marketing, investigation, and control of such drugs or other substances.

The Committee shall consist of a core of 11 voting members including the Chair. Members and the Chair are selected by the Commissioner or designee from among authorities knowledgeable in the fields of risk communication, risk management, drug safety, medical, behavioral, and biological sciences as they apply to risk management, and drug abuse. Members will be invited to serve for overlapping terms of up to 4 years. Almost all non-Federal members of this committee serve as Special Government Employees. The core of voting members may include one technically qualified member, selected by the Commissioner or designee, who is identified with consumer interests and is recommended by either a consortium of consumer-oriented organizations or other interested persons. In addition to the voting members, the Committee may include one non-voting member who is identified with industry interests.

Further information regarding the most recent charter and other information can be found at

<http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/DrugSafetyandRiskManagementAdvisoryCommittee/ucm094886.htm> or by contacting the Designated Federal Officer (see FOR FURTHER INFORMATION CONTACT). In light of the fact that no change has been made to the committee name or description of duties, no amendment will be made to 21 CFR 14.100.

This document is issued under the Federal Advisory Committee Act (5 U.S.C. app.). For general information related to FDA advisory committees, please visit us at <http://www.fda.gov/AdvisoryCommittees/default.htm>.

Dated: May 13, 2016.

Jill Hartzler Warner,

Associate Commissioner for Special Medical Programs.

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